

Food and Drug Administration College Park, MD 20740

3 2 4 3 5 AUG 18 P2:20 AUG 16 2005

Mr. Gene C. Weitz President and CEO SmartScience Laboratories, Inc. 2327 Destiny Way Odessa, Florida 33556

Dear Mr. Weitz:

This is in response to your letters of July 1, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that SmartScience Laboratories, Inc. intends to make the following claims in the labeling of the product ReStoreTM:

- "[C]an be taken two ways: at the first sign of cold symptoms..."
- "[D]eveloped this product because I was sick of catching colds."
- "Take at the first sign of cold symptoms...."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease, namely the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Page 2 - Mr. Gene C. Weitz

Please contact us if we may be of further assistance.

Sincerely yours,

for Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Florida District Office, Office of Compliance, HFR-SE-240



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

1 July 2005 2005

fax: 727-375-9062 RE: www.jointflex.com

Label Claims / Disclaimers

SmartScience Laboratories Inc. Reference No. 1006

Dear Sir / Madam:

This letter is to notify you that SmartScience Laboratories Inc., at 2327 Destiny Way, Odessa, Florida 33556, is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug and Cosmetic Act on the labels of the following product.

COMPANY

SmartScience Laboratories Inc.

PRODUCT NAME

ReStore™

DIETARY INGREDIENTS

Vitamin A, Vitamin C, Vitamin E, Magnesium Sulfate, Zinc Sulfate, Sodium Selenite, Manganese Gluconate, Potassium Bicarbonate, Herbal Extracts (Lonicera, Forsythia, Schizonepeta, Ginger, Chinese Vitex, Isatis Root, Echinacea), Amino Acids (Glutamine, Lysine).

STATEMENTS

. . . can be taken two ways: at the first sign of cold symptoms or before entering crowded environments, like airplanes and offices.

I certify that the information contained in this notice is complete and accurate and the SmartScience Laboratories Inc. has substantiation that the statements are truthful and not misleading.

Bv:

Gene C. Weitz

If you have any questions, please contact Gene C. Weitz, President & CEO, at 727-375-5911, ext. 204.

Sincerely,

Gene C. Weitz

President & CEO

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05-4867



www.iointflex.com

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Label Claims / Disclaimers

SmartScience Laboratories Inc. Reference No. 1005

JUL - 6 2005

1 July 2005-

Dear Sir / Madam:

This letter is to notify you that SmartScience Laboratories Inc., at 2327 Destiny Way, Odessa, Florida 33556, is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug and Cosmetic Act on the labels of the following product.

COMPANY

SmartScience Laboratories Inc.

PRODUCT NAME

ReStore™

DIETARY INGREDIENTS

Vitamin A, Vitamin C, Vitamin E, Magnesium Sulfate, Zinc Sulfate, Sodium Selenite, Manganese Gluconate, Potassium Bicarbonate, Herbal Extracts (Lonicera, Forsythia, Schizonepeta, Ginger, Chinese Vitex, Isatis Root, Echinacea), Amino Acids (Glutamine, Lysine).

STATEMENTS

. . . developed this product because I was sick of catching colds.

I certify that the information contained in this notice is complete and accurate and the SmartScience Laboratories Inc. has substantiation that the statements are truthful and not misleading.

sy: ___

Gene C. Weitz

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If you have any questions, please contact Gene C. Weitz, President & CEO, at 727-375-5911, ext. 204.

Sincerely,

Gene C. Weitz President & CEO



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

JUL - 6 2005

1 July 2005

RE:

Label Claims / Disclaimers

SmartScience Laboratories Inc. Reference No. 1004

Dear Sir / Madam:

This letter is to notify you that SmartScience Laboratories Inc., at 2327 Destiny Way, Odessa, Florida 33556, is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug and Cosmetic Act on the labels of the following product.

COMPANY

SmartScience Laboratories Inc.

PRODUCT NAME

ReStore™

DIETARY INGREDIENTS

Vitamin A, Vitamin C, Vitamin E, Magnesium Sulfate, Zinc Sulfate, Sodium Selenite, Manganese Gluconate, Potassium Bicarbonate, Herbal Extracts (Lonicera, Forsythia, Schizonepeta, Ginger, Chinese Vitex, Isatis Root, Echinacea), Amino Acids (Glutamine, Lysine).

STATEMENTS

Take at the first sign of cold symptoms or in crowded places.

I certify that the information contained in this notice is complete and accurate and the SmartScience Laboratories Inc. has substantiation that the statements are truthful and not misleading.

Rv.

Gene C. Weitz

If you have any questions, please contact Gene C. Weitz, President & CEO, at 727-375-5911, ext. 204.

Sincerely,

Gene C. Weitz

President & CEO